

REMARKS

Claims 1-9, 11-28 and 30-43 are currently pending in the present application. Claims 1-8 and 37-43 are withdrawn from consideration. Claims 9, 11, 16, 21 and 27 are amended solely in order to expedite prosecution. The amendments are supported in figures 23-31 as well as paragraphs [0200]–[0221] of the originally filed application, among other places. No new matter is added.

Applicants respectfully submit that the Office Action Summary Form PTOL-326 mailed with the most recent Office Action incorrectly lists the disposition of the pending claims. Applicants submit that claims 1-9, 11-28 and 30-43 are pending, although some may be withdrawn, and request that further communications from the Examiner include a correct listing of the claims.

Claim Rejections – 35 U.S.C. 102(b)

Claims 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No 4,583,540 to Malmin (hereinafter "Malmin"). Applicants traverse this rejection.

A claim is not anticipated or rendered obvious if each and every element of the claim is not found, either expressly or inherently, in the prior art references. See MPEP 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Malmin describes skewers for puncturing a scalp and forming a passageway for the insertion of hair strands. Malmin's skewers include one or more strand carrying pockets. Malmin describes both single pockets that carry one strand in one direction and double pockets that engage more than one strand for movement in two directions. *See* Malmin, col. 6, lines 25-33. Malmin states that a pocket's depth "must be sufficient to receive and retain the thickness of the strand." *See* Malmin, col. 10, lines 40-41. Malmin is silent on the width of the pockets.

Claim 16

Applicants' amended claim 16 recites a connector pair for attaching a medical implant to a delivery device. The connector pair includes a closed loop connector located at an end of a medical implant and a slotted connector formed in a distal end of a shaft of a delivery device for interfitting with the closed loop connector of the medical implant. The slotted connector includes first and second legs, wherein the first leg extends radially into the shaft and the second leg extends axially in a distal direction along the shaft. The second leg is substantially spherical in shape and has an opening for accepting the looped connector at an intersection with the first leg. The opening has a width that is less than a thickness of a portion of the loop connector that passes through the opening to interfit the slotted connector with the loop connector.

Malmin neither shows nor suggests Applicants' connector pair of claim 16 including a slotted connector with a second leg having an opening for accepting a looped connector, wherein the opening has a width that is less than a thickness of a portion of the loop connector that passes through the opening to interfit the slotted connector with the loop connector. Applicants respectfully submit that Malmin is silent on the width of his strand carrying pockets and none of the Malmin figures show a pocket with a width that is less than a strand. Accordingly, Malmin cannot anticipate Applicants' claim 16.

Claim 18

Applicants' claim 18 recites a connector pair for attaching a medical implant to a delivery device. The connector pair includes a closed loop connector located at an end of a medical implant and a slotted connector formed in a distal end of a shaft of a delivery device for interfitting with the closed loop connector of the medical implant. The slotted connector includes first and second legs, wherein the first leg extends radially into the shaft and the second leg extends axially in a distal direction from the first leg along the shaft. The second leg is longer than the first leg and includes a curved portion.

Malmin does not show or suggest Applicants' connector pair of claim 18 including a shaft with a slotted connector having first and second legs, wherein the second leg extends axially in a

distal direction along the shaft and is longer than the first leg. In rejecting claim 18, the Examiner references pocket 110c of Malmin without acknowledging claim 18's feature of a second leg that is longer than the first leg. *See* Office Action, page 3. Applicants respectfully submit that figure 10 or any other portion of Malmin does not show a pocket having this feature. In fact, Malmin merely states that a pocket's depth "must be sufficient to receive and retain the thickness of the strand." *See* Malmin, col. 10, lines 40-41.

For at least the above reasons, Applicants respectfully request that the rejection of claims 16 and 18, and all claims dependent thereon, be withdrawn.

Claim Rejections – 35 U.S.C. 103(a) - Giesy in view of Ferguson

Claims 9, 11-13, 21-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,152,749 to Giesy et al. (hereinafter "Giesy") in view of U.S. Patent No 3,877,434 to Ferguson et al. (hereinafter "Ferguson"). Applicants traverse this rejection.

Giesy describes a catheter delivery device. Giesy's device includes a needle having an indentation for receiving a loop that is connected to a catheter. Giesy's device also includes a sheath that is biased to advance distally over the needle to cover the indentation and lockingly engage the loop with the indentation. *See* Giesy, col. 6, lines 60-68 and col. 7, lines 1-5.

Ferguson describes a vascular tourniquet with a hook for grasping a cord. The tourniquet's hook includes an opening that tapers from its open proximal end to its closed distal end. Ferguson states that this configuration permits easy lateral insertion of the cord. *See* Ferguson, col. 3, lines 27-30.

Claims 9 and 11

Applicants' amended claim 9 recites a connector pair for attaching a medical implant to a delivery device. The connector pair includes a closed loop connector located at an end of a medical implant and a slotted connector formed in a distal end of a shaft of a delivery device for interfitting

with the closed loop connector of the medical implant. The slotted connector includes first and second legs, wherein the first leg extends radially into the shaft and the second leg extends axially in a distal direction from the first leg along the shaft. The second leg is longer than the first leg and includes a narrowing for locking the looped connector into the second leg. The first and second legs join at an inside corner and an outside corner, the outside corner being located proximal to the inside corner along the shaft.

Neither Giesy, nor Ferguson, nor any combination of these two references shows or suggests Applicants' connector pair of claim 9. As conceded by the Examiner, Giesy fails to disclose a narrowing. *See* Office Action, page 5. Ferguson shows a tapered opening but does not show first and second legs joined at an inside corner and an outside corner, with the outside corner being located proximal to the inside corner along the shaft. *See* Figures 1 and 4 of Ferguson. A combination of references that does not show all of the limitations of the Applicants' claims cannot render those claims unpatentable.

With respect to claim 11, Applicants respectfully point out that the legs of the Ferguson device are not taught or disclosed as extending substantially perpendicular to each other, as provided in amended claim 11.

Claim 21

Applicants' amended claim 21 recites a connector pair for attaching a medical implant to a delivery device. The connector pair includes a closed loop connector located at an end of a medical implant and a slotted connector formed in a distal end of a shaft of a delivery device for interfitting with the closed loop connector of the medical implant. The slotted connector includes first and second legs, wherein the first leg extends radially into the shaft and the second leg extends axially in a distal direction from the first leg along the shaft. The second leg is longer than the first leg. The connector pair also includes a slidable tubular sleeve on the shaft for sliding over and covering the slotted connector subsequent to interfitting the closed loop connector with the slotted connector.

The tubular sleeve is unpowered, except for an operator's manipulation, when it slides over the slotted connector.

Neither Giesy, nor Ferguson, nor any combination of these two references shows or suggests Applicants' connector pair of claim 21 including a slotted connector and a slidable tubular sleeve for sliding over and covering the slotted connector subsequent to interfitting a closed loop connector with the slotted connector, wherein the sleeve is unpowered, except for an operator's manipulation, when it slides over the slotted connector. Giesy's catheter delivery device includes a sheath that is biased to extend by a spring in the device's handle. *See* Giesy, col. 6, lines 1-5. Accordingly, Giesy's sheath is powered when it slides over the indentation. The tourniquet described in Ferguson includes a sheath and a retractor with a hook for grasping the loose ends of an umbilical cord. *See* Ferguson, col. 3, lines 9-18. Applicants submit that a hook grasping the loose ends of an umbilical cord and retracting through a sheath cannot reasonably be characterized as a tubular sleeve for sliding over and covering a slotted connector subsequent to interfitting a closed loop connector with the slotted connector.

Applicants traverse the Examiner's statement that, "it would have been an obvious matter of design choice to provide the sleeve past the loop portion and onto the implant." *See* Office Action, page 7. The Examiner has not identified a passage from the Giesy or Ferguson references supporting such an assertion, nor has the Examiner cited any other reference to provide such support.*

Moreover, Applicants respectfully submit that Giesy's catheter delivery device would not be operable when combined with Ferguson's hook. The Giesy device includes a sheath such that a catheter's loop can be lockingly engaged with an indentation while the catheter is being positioned. After the catheter is in place, Giesy's sheath can be pulled back such that the catheter's loop is easily released from the indentation. *See* Giesy, col. 7, lines 43-48. Ferguson's hook has a tapered opening such that the ends of a cord can be wedged into tight frictional engagement with the hook.

* The Examiner has effectively taken "official notice." Applicants take no position at this time as to whether, in doing so, the Examiner has met the requirements of MPEP § 2144.03.

See Ferguson, col. 3, lines 27-31. If the two references were combined, the tapered opening of Ferguson's hook would wedge a catheter's loop into a "frictional engagement" that would make it difficult to subsequently release the loop from the hook as taught in Giesy. *See* Office Action, page 6. Accordingly, the Examiner's suggested combination of Ferguson and Giesy would eviscerate the spirit of the Giesy reference and render it inoperable for its primary purpose.

For at least the above reasons, Applicants respectfully request that the rejection of claims 9 and 21, and all claims dependent thereon, be withdrawn.

Claim Rejections – 35 U.S.C. 103(a) - Giesy in view of Skiba

Claims 27, 28 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy in view of U.S. Patent No. 6,723,107 to Skiba (hereinafter "Skiba"). Applicants traverse this rejection.

Skiba describes a device for delivering sutures. Skiba shows various tips that can be provided on his device. Some of Skiba's tips include an eyelet with a tapered central portion while others include a side-loading eyelet with a tapered configuration. *See* Skiba, col. 3, lines 60-65 and col. 4, lines 27-33.

Applicants' claim 27 recites a connector pair for attaching a medical implant to a delivery device. The connector pair includes a closed loop connector located at an end of a medical implant and a slotted connector formed in a distal end of a shaft of a delivery device for interfitting with the closed loop connector of the medical implant. The slotted connector extends obliquely into the shaft from a first location to a second location, wherein the second location is further distal along the shaft than the first location. The slotted connector also includes a narrowing, wherein the narrowing includes a protuberance in a wall of the slotted connector, and the slotted connector is wider than the narrowing at a location between the protuberance and the second location.

Neither Giesy, nor Skiba, nor any combination of these two references shows or suggests Applicants' connector pair of claim 27 including a slotted connector for interfitting with a closed

loop connector, extending obliquely into a shaft from a first location to a second location and having a narrowing, wherein the narrowing includes a protuberance in a wall of the slotted connector and the slotted connector is wider than the narrowing at a location between the protuberance and the second location. As admitted by the Examiner, Giesy fails to teach a slotted connector having a narrowing, wherein the narrowing includes a protuberance in a wall of the slotted connector. *See* Office Action, page 9. To compensate for this deficiency in the Giesy reference, the Examiner introduces Skiba, with specific reference to figures 12 and 16 of Skiba. Applicants submit, however, that the eyelet shown in figure 12 of Skiba is not a slotted connector for receiving a closed loop connector but rather a lumen for receiving the loose end of a suture. *See* Skiba, figure 3. As for figure 16, the eyelet shown therein includes a tapered portion, but the eyelet merely tapers to a slot rather than widening again.

For at least the above reasons, Applicants respectfully request that the rejection of claim 27, and all claims dependent thereon, be withdrawn.

Claim Rejections – 35 U.S.C. 103(a) – Various Combinations

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Giesy in view of Ferguson and further in view of Skiba. Claims 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmin in view of Ferguson. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy in view of Ferguson and further in view of U.S. Patent No. 5,439,467 to Benderev et al. (hereinafter "Benderev"). Applicants traverse these rejections.

Applicants submit that the above dependent claims are allowable because each depends from an allowable base claim, as shown above. Accordingly, Applicants request that the rejection of these dependent claims be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.

A petition for a three-month extension of time is being submitted herewith, and Applicants hereby requests that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**, under Order No. MIY-P03-024 from which the undersigned is authorized to draw.

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Respectfully submitted,

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